REMARKS

Claims 1-52 remain pending in the application. New claims 21-52 have been added. All other claims remain unchanged. Reconsideration of the pending claims is respectfully requested.

New claims 21-40 cover narrower embodiments of original claims 1-20 except that the new claims require the presence of the external drug-containing coating; whereas original claims 1-20 define the coating as being optional.

New claims 41-42 specify the time period within which drug is released from the drug-containing external coating. Support for this subject matter is found in the original specification (page 4, lines 2, 17-18).

New claim 43 specifies the environments in which the inert water soluble and/or erodible coating is soluble. Support for this subject matter is found in the original specification (page 14, lines 17-20).

New claims 44, 50 and 51 specify the osmopolymer. Support for this subject matter is found in the original specification (page 28, table; page 29, table).

New claim 45 defines the release profile of drug released from the core of the device. Support for this subject matter is found in the original specification (page 10, table between lines 9 and 10).

New claim 46 defines the release profile of drug released from the core of the device. Support for this subject matter is found in the original specification (page 10, table below line 15, second column, Percent Released B).

New claim 47 defines the release profile of drug released from the core of the device. Support for this subject matter is found in the original specification (page 10, table below line 15, third column, Percent Released C).

New claim 48 defines the composition of the device. Support for this subject matter is found in the original specification (Example 4, page 34).

New claim 49 defines the osmagent. Support for this subject matter is found in the original specification (page 19, line 16; Example 1, page 28; Example 2, page 29).

New claim 52 defines the water erodible material in the inert coating. Support for this subject matter is found in the original specification (page 4, line 16; page 13, line 29; page 15, lines 6-10).

Claims 1-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wong et al. (U.S. Pat. No. 4,783,337) and Theeuwes et al. (U.S. Pat. No. 4,077,407) in combination, and further in view of Faour (U.S. Pat. No. 6,352,721). Examiner cites each of the three patents as disclosing various osmotic devices of differing constructions and containing various different drugs. Examiner acknowledges that none of them specifically teaches or discloses the inclusion of licofelone in an osmotic device but then states that doing so would be obvious. Insofar as it may apply to the present claims, this rejection is respectfully traversed.

Applicants acknowledge that osmotic devices are known controlled release devices that provide a continuous release of a pharmacologically active agent over an extended period of time. However, Applicants submit Examiner has inadvertently applied hindsight reconstruction of the invention absent a motivation by the cited art to arrive at the claimed invention.

The art fails to disclose or suggest the advantages of and fails to provide motivation for administering licofelone with a controlled release device or an osmotic device. Indeed, one of the key reasons to use controlled release devices is to provide sustained therapeutically effective plasma concentrations of a drug in a subject, wherein the drug has a short half-life. This is because such drugs are rapidly metabolized, and it is difficult to sustain therapeutically effective plasma concentrations of the drug over a prolonged period of time when using conventional rapid or immediate release dosage forms. However, absent hindsight reconstruction, there is little motivation for an artisan to place a drug with a long half-life in a controlled release dosage form. This is because such drug has a prolonged residence time in the plasma even after administration with a conventional rapid or immediate release dosage form, so therapeutically effective concentrations of such drug are easily achieved without need of a controlled release dosage form.

As indicated in the Background section of the present application, licofelone exhibits an elimination half-life ($T_{1/2}$b) of about 8.7-11.1 hours (Albrecht W. et al., *Annual European Congress of Rheumatology*, EULAR 2002, abstr. AB0293 12 Jun. 2002). This means that therapeutically effective plasma concentrations of licofelone can be easily achieved and maintained when administered with a conventional rapid or immediate release dosage form. That being the case, Applicants question why the artisan, absent hindsight reconstruction, would be motivated to include licofelone in a controlled release dosage form.

Applicants respectfully advise Examiner of the following case law.

1. The prior art reference or combination of references must teach or suggest all the limitations of the claims. (*In re Wilson* 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970)

   In this regard, the prior art does not teach or suggest a prophetic combination of licofelone in a controlled release dosage form or an osmotic device. Moreover, the prior art fails to teach or suggest such dosage forms, covered by the dependent claims, wherein the composition of the dosage form and the drug release profiles of the dosage form are defined.

2. The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. (*In re Greiger* 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987) The mere fact that the prior art can be so modified does not make the modification obvious unless the prior art suggests the desirability of the modification. (*In re Godeon* 733 F.2d 900, 902, 221 U.S.P.Q.1125, 1127 (Fed. Cir. 1984). The Federal Circuit has repeatedly warned that the requisite motivation must come from the prior art, not applicants' specification. (*In re Dow Chem. Co. v. American Cyanamid Co.,* 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988). There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicants' disclosure. Using an applicants' disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of §103 which requires judging obviousness at the point in time when the invention was made. (*In re Grain Processing Corp. v. American Maize-Prods. Co.,* 840 F.2d 902,907, 5 U.S.P.Q.2d 1788 (Fed. Cir. 1988) Care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. (*Id.* At 907, 5 U.S.P.Q.2d at 1792).

   In this regard, Applicants note the arguments above and question where the cited references provide the motivation to make the proposed prophetic combination. Examiner has combined two or three osmotic device-related references and has still failed

to arrive at a prophetic combination that includes licofelone in an osmotic device or controlled release dosage form as defined in the instant claims. Even if one improperly picks and chooses bits and pieces of the cited art, one does not arrive at the claimed combination of elements.

Accordingly, Applicants submit that the rejection of claims 1-20 under 35 U.S.C. 103(a) has been overcome and request that it be withdrawn.

Applicants have made a diligent effort to advance the prosecution of the application by amending the claims and presenting arguments in support of patentability. In view of the above, Applicants submit that the claims are in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

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